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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,815	10/18/2001	Wolfgang Muhlbauer	GLAWE-06599	5359

7590 11/17/2004

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,815

Applicant(s)

MUHLBAUER ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27, 2004 has been entered.

Claims 12, 14-25 are pending.

Any rejection that is not addressed in this Office Action is obviated in view of the claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 12, 14-18, 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fues et al US Patent 5,143,730 in view of Clark US Patent 4,847,083.

The instant claims are directed to methods of dressing a bone comprising providing a composition comprising at least one wax such as wax alcohols or oxidates thereof and a metal hydroxide, applying the composition to the bone or in the bone and stimulating collagen regeneration in the bone.

Fues teaches solid waxes for treating or regenerating hard body tissues such as bones. (abstract, col 5, lines 60-64). The waxes of Fues are produced by glycerol or glycerol esters which fall within the limitations of the instant wax alcohols in amounts of about 50% (see col 3, lines 14-19; col 4, lines 60-65; col 5, lines 1-10; col 6, lines 19-35; col 6, lines 30-35). The composition of Fues also contains an earth alkali metal hydroxide such as hydroxylapatite (see col 4, line 14; col 7, lines 33-35). The composition of Fues contains at least one additional substance such as calcium lactate in amount of upto 20% and upto 95% oligomers of lactic acids which meets the limitations of instant claim 18. (see col 5, lines 30-35; col 8, lines 55-58). Since compositions of Fues meet all elements of the instant compositions, they would also exhibit its alkalinity release. Fues does not explicitly describe that his compositions would stimulate collagen regeneration in the bone.

Clark is used to show that production of lactic acid at the wound site, exogenously or endogenously, would stimulate formation of collagen (see col 2, lines 40-50).

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Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention, to provide collagen formation at the site of bone injury when applying the lactic acid containing compositions of Fues, because as described by Clark formation of lactic acid, endogenously by the injury or exogenously by applying Fues' compositions, at the site of injury would have led to regeneration and thus formation of collagen. Therefore, one of ordinary skill in the art would have had a reasonable expectation of observing a local stimulation of collagen regeneration at the site where Fues's composition would have been applied.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fues et al US Patent 5,143,730 in view of Clark US Patent 4,847,083 as applied to claims 12, 14-18 and 20-25 and further in view of Thiele US Patent 3,805,776.

The teachings of Fues and Clark are described above. the combined teaching of Fues and Clark do not employ vegetable oils such as castor oil or sunflower oil in their compositions.

Thiele is used to show that hydrogenated vegetable or animal fatty acids such as castor oil fatty acids are suitable vehicles for delivery of compositions that minimize bone degeneration at a site of bone injury. Thiele shows that such vegetable oil vehicles, such as castor oil, are readily used for local administrations of drugs into the bony area to treat osteolysis of the bone. (see col 3, lines 30-35).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to further modify the compositions of Fues to include a vegetable oil such as castor oil, because as described by Thiele, one of ordinary skill in the art would

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have had a reasonable expectation of success in improving the delivery of suitable therapeutic agents at the bony area.


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**